Guide to the Information Sheet & Informed Consent Form for Research Participants

All research projects that involve people and sometimes their data, require a detailed statement, written in clear language, that meets the information needs of prospective participants.

The purpose of the Information Sheet for Participants (ISP) is to explain the research project, identify what will be asked of research participants, and outline the risks and safeguards that are in place so that true informed consent for participation can be obtained. The form should be succinct (2-3 pages), written in language that is 'in tune' with participants and provide enough detail to enable them to make an informed decision about whether they want to contribute to the study or not.

The material below provides a guide only. It outlines what is required, however, researchers should tailor or add information to suit their project. Where the research is being conducted in partnership with another agency, the guidelines of that agency relating to participant information should be combined with these guidelines.

A single Information Sheet is usually enough for most projects. However, more complex projects may involve groups of participants, for example, school students and teachers, service providers and clients, where differing inputs are sought. In such circumstances, more than one Information Sheet might be needed. If different types of data are collected from the same group of participants then only one Information Sheet is required; it just needs to mention all the modes (e.g. interview, observation, survey).

The ISP should be on LETTERHEAD and appropriately branded. The full contact details of the researcher and organisation(s) conducting the research should appear clearly as a header or footer and in the text, towards the end.

The Information Sheet for Participants

Project title: The formal title of the study should appear prominently, centred at the top of the page in large bold type. An additional participant-friendly and welcoming subtitle can be added that appears larger and brighter (if colour is used) to engage participants.

Information Sheet: inserted at the top left of the page with the words 'This is yours to keep for reference'.

Introduction: The researchers, including students, should introduce themselves, the justification and purpose of the study. Add the full details of the PI: personal title, name, academic qualification and section/branch/organisation of the principal researcher at the end of the form under a heading: For more information about the study contact:

If you are a student, insert your personal title, name, and your course of study. If there are associate supervisors, give the personal title, name, qualification, School and University or parent agency, of the assistants.

Study aim(s): insert the aim(s) of the research in lay terms, without jargon.

Benefits and risks of the project: Briefly describe the benefits of the research to the participants and/or to the field of study. The benefits should be realistic and reflect the level and complexity of the proposed research. Mention all the possible risks that might be experienced in course of the study and address how they will be minimised.

General outline of the project: Provide a brief overview of the study methods, indicate from whom the data will be collected; explain how the data will be collected, analysed and presented, and if /how the results will be shared with participants and the academic community.

Participant involvement: Describe what the participants will be asked to do, for example, complete a survey questionnaire, undertake an interview, participate in a focus group and/or permit access to personal records. Include how much time each mode of data collection might take. For qualitative methodologies, identify how the data will be recorded. If data are recorded by note taking or by video/tape recorder and then transcribed for analysis, indicate what will happen to a participant's data should that participant decide to withdraw from the project.

The place of data collection, the number of occasions that participants will be required and the approximate time commitment involved needs to be indicated clearly.

Also include:

- The *voluntary* nature of the project
- That a participant can withdraw at any time without explanation or penalty
- That a participant can decline to answer a question

Indicate if any remuneration will be given. Where relevant, identify what this is, how it will be provided and repeat the information in the consent form.

Inclusion and exclusion criteria: Mention why they have been asked to participate in the study and detail the reasons that would exclude potential participants if relevant.

Confidentiality: Indicate who will have access to the data provided by the participants e.g. members of the research team, transcriber, research supervisor.

Anonymity: Indicate whether the anonymity of the participants is to be preserved, and if so, how this will be done in dissertations, publications, reports, presentations or teaching as is relevant.

Data storage: Indicate where the data will be stored and how security of personal information will be maintained during collection, analysis and writing up of results. This should be succinct but enough detail for participants to understand.

Participants should also be informed where the data will be stored once the project is complete. Normally this will be at the host institution that accepts responsibility for the research for a period of five years.

Different locations and longer periods may apply if the research is conducted with other agencies. Identify what will happen to the data at the end of the storage period.

Human research ethics clearance: Include a statement that the project has been approved by the Charles Darwin University Human Research Ethics Committee. If the project has gained approval from other ethics committees or authorities, include a statement to that effect that identifies the relevant bodies.

For more information about the study: Requests for further information or queries about the study should be directed to the Principal Investigator. Provide name and contact details.

Concerns regarding ethical conduct must be directed to the Ethics Committee. The following mandatory statement are required:

> If you have any questions or concerns that you do not want to direct to the researcher, you are invited to contact the Charles Darwin University Research Integrity and Ethics team on (08) 89466063, toll-free number, 1800 466 215 or by email, ethics@cdu.edu.au.
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> The Research Integrity and Ethics team can pass on any concerns to the Charles Darwin University Human Research Ethics Committee (CDU-HREC) and appropriate officers within the University.

The Informed Consent Form

The guiding principle for consent is that any agreement to participate is voluntary and based on information that is sufficient, clear and unambiguous and provided in the Information Sheet for Participants. The Informed Consent Form provides evidence of an agreement between the research and the participant on the conditions, rights and obligations of both parties to conduct the research according to your project plan. Substantiation of informed consent can take several forms. It is most often given by signing a consent form but under certain circumstances, consent may be given verbally. Consent may also be given implicitly, for example by completion of a survey.

The Informed Consent form should reflect accurately each proposed intervention for which participant permission is sought, e.g., the proposed level of confidentiality, the right to say no or to withdraw without explanation. Any payment or that no payment will be provided should be made clear.

When permission to take photographs or record videos is sought or when seeking to use the data for future research, a 'tick all that apply' or Yes/No option may be helpful, as it enables participation while respecting individual preferences i.e. participants can opt out of photographs but still be interviewed.

Further essential information includes the research institution, study title and name of the researcher(s), including any additional partners or agencies involved, as well as a statement of acknowledgement by participants that they have read the Information Sheet for Participants, and understand the nature of their involvement and have had an opportunity to ask questions.

For more information, please refer to National Statement Chapter 2.2.